UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

STEUBEN FOODS, INC.,	**REPORT AND RECOMMENDATION**
v.	
Plaintiff,	**1:10-cv-00780-EAW-JJM**
	1:10-cv-00781-EAW-JJM
OYSTAR GROUP, ET AL.,	**1:12-cv-00904-EAW-JJM**
	1:13-cv-00892-EAW-JJM
	1:13-cv-01118-EAW-JJM
Defendants.	

INTRODUCTION

The parties are generally familiar with the nature of these five patent infringement actions which, although not formally consolidated, are being handled on a parallel track for purposes of pretrial proceedings. This Report and Recommendation addresses the question of whether the phrase "aseptically disinfecting", contained in several claims of the patents in suit, can be validly construed and/or applied to cover the use of a sterilant known as oxonia, which is utilized by some of the defendants.

"The inventions described in Steuben's patents-in-suit provide an aseptic packaging system for processing bottles at a high output processing speed, and which can meet the stringent United States FDA [Food and Drug Administration] aseptic standards." Steuben's Opening Markman Submission [417], p. 5.[1] "To meet the FDA standards, the bottles must be disinfected before filling them with a sterile product. Generally, aseptic disinfection of a package involves application of a chemical sterilant (*e.g.*, hydrogen peroxide or oxonia (hydrogen peroxide and peroxyacetic acid)), followed by removal of the sterilant using a sterile fluid rinse

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[1] Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). Unless otherwise indicated, bracketed references are to CM/ECF docket entries in 12-cv-904, and page references are to the documents themselves rather than to CM/ECF pagination.

(*e.g.*, water or air). The challenge of aseptically disinfecting bottles is at the heart of Steuben's patents." Id., p. 6.

On January 31, 2018 I held a Markman hearing addressing the proper construction of the phrase "aseptically disinfecting" [485]. Since that time, my views on the topic have continued to evolve.[2] *See* my three Rule 56(f)(3) Notices [486, 497, 517] and two Decisions and Orders [501, 516]. In addition, defendants have moved for partial summary judgment on the question.[3]

Although the parties have urged various constructions of "aseptically disinfecting", for present purposes I need only conclude that whatever else it may mean, the phrase cannot validly cover the use of oxonia as the sterilant. *See* Vivid Technologies, Inc. v. American Science & Engineering, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) ("terms need be construed . . . only to the extent necessary to resolve the controversy").

BACKGROUND

The phrase "aseptically disinfecting" appears in most of the patent claims. *See*, *e.g.*, U.S. patent no. 6,945,013 (the "'013 patent") [1-1], claims 1-20.[4] The patents define the term "aseptic" to mean "the United States FDA level of aseptic" ('013 patent, col. 2, l. 1-2), U.S. patent no. 6,536,188 ("'188 patent") [426-3], col. 4, l. 26-27), and the Federal Circuit has adopted that definition as "a binding lexicography". Nestle USA, Inc. v. Steuben Foods, Inc.,

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[2] The court is free to "modify pre-trial rulings and interlocutory orders at any time prior to final judgment". Ifedigbo v. Buffalo Public Schools, 2018 WL 2901331, *1 (W.D.N.Y. 2018); Fed.R.Civ.P. ("Rule") Rule 54(b).

[3] [506] in 12-cv-904, [399] in 10-cv-781, [245] in 13-cv-1118, [292] in 10-cv-780, [335] in 13-cv-892.

[4] Although much of this Report and Recommendation addresses the '013 patent, except as discussed herein the same analysis applies to the other patents in suit, as they are related.

686 Fed. App'x 917, 919 (Fed. Cir. 2017). The Federal Circuit also "confine[d] an 'FDA level of aseptic' to FDA regulations related to aseptic packaging" (id.). One of those regulations is 21 C.F.R. §113(e)(2), allowing the use of "chemical sterilant(s)" to obtain "commercial sterility". However, "[a]t the time of filing [for the patents in suit] (February 2, 1999) . . . hydrogen peroxide was the only FDA approved sterilant". Steuben's Response, [427-14], p. 41. Hydrogen peroxide was approved pursuant to another "aseptic packaging" regulation, 21 C.F.R. §178.1005.[5]

When asked at his deposition whether "the term 'aseptic disinfecting' . . . require[s] the use of an FDA-approved sterilant", Thomas Taggart, the listed inventor of the patents in suit, responded "Yes. That's what I think it's supposed to mean". [427-11], p. 386. That position is corroborated by the "Background of the Invention" portion of the patent specifications, stating that "[f]or the aseptic packaging of food products, an aseptic filler must . . . use an FDA (Food and Drug Administration) approved sterilant". *See, e.g.*, '013 patent) [1-1], col. 1, l. 48-50 and '188 patent [426-3], col. 1, l. 46-48.

Steuben quoted that statement as an example of the "lexicography" which "makes clear that the methods of the invention are FDA-compliant". Steuben's Response [427-14], pp. 32-33. At the Markman hearing, Steuben's counsel acknowledged that "the discussion of FDA-approved sterilant is in the background. *You're going to have to meet that*. That's what [Taggart] recognized." [485], p. 28 (emphasis added). And although hydrogen peroxide was the only FDA-approved sterilant at the time of the patent applications, Steuben contends that Taggart "invented a system that could meet [FDA approval] using either hydrogen peroxide or oxonia" as the

[5] "[I]n 1979, an aseptic packaging company named Tetra Brik filed a food additive petition under [21 U.S.C.] §348 for hydrogen peroxide . . . . That petition resulted in the issuance of 21 C.F.R. § 178.1005, which deemed hydrogen peroxide solutions safe for the specific use of sterilizing aseptic packaging materials to achieve commercial sterility under 21 C.F.R. §113." Steuben's Response [476], p. 4.

sterilant. Id. *See* '013 patent [1-1], col. 7, l. 3-4; '188 patent [426-3], col. 7, l. 3-4 ("[t]his sterilant may be hydrogen peroxide or oxonia (hydrogen peroxide and peroxyacetic acid)"); Steuben's Memorandum of Law [492], p. 25 ("Steuben's patent specification describes the use of both hydrogen peroxide and oxonia as a chemical sterilant as being part of the invention").

However, prior to filing his patent applications, Taggart had never used oxonia as a sterilant. [427-11], p. 168. He testified that it was not being used as a sterilant in the United States at the time of his applications, in part because "there was a technical paper that was out there at the time that found that Oxonia and peracetic acid wasn't as effective". Id., p. 170.[6] *See* Blakistone, *et al.*, "Efficacy of Oxonia Active Against Selected Spore Formers" (expressing "concern about the efficacy of the sterilant for aseptic packaging of low-acid foods", and suggesting that "[f]urther work will be needed"). [427-19], p. 2 of 7 (CM/ECF pagination). Taggart testified that he did not "know the effectiveness of [oxonia's components] peracetic acid and . . . hydrogen peroxide alone or together", nor "the amount of each component required to act as a sterilant". [427-11], p. 232.

Recognizing that "a combination of hydrogen peroxide and peracetic acid [a/k/a oxonia] was used worldwide as a sterilant, but not in the FDA aseptic field", Taggart stated that "if some testing was done and the right data was presented to the FDA, they might approve it". Id., p. 227. However, he never tested oxonia for use as a sterilant in his invention. Id., p. 167. Instead, he used hydrogen peroxide because it "was approved . . . . I knew that if I used a different sterilant that wasn't already approved, there would be much more testing that would be required". Id., p. 198.

[6] Although Mr. Taggart referred to "peracetic" rather than "peroxyacetic" acid, the parties agree that the terms are synonymous. April 10, 2018 proceeding [500], p. 13.

Nevertheless, not only did the patent specifications state that oxonia could be used as the sterilant, but on September 12, 2013 - *after* Steuben had commenced four of these five actions,[7] Taggart obtained an Ex Parte Reexamination Certificate for the '188 patent adding claim 40, which specifically mentioned oxonia as a limitation ("aseptically disinfecting the plurality of bottles . . . wherein the sterilant is peroxyacetic acid and hydrogen peroxide"). [426-3], pp. 27, 30 (CM/ECF pagination).

DISCUSSION

A. Could Taggart Satisfy the Requirements for FDA Approval of Oxonia?

Defendant Nestle argues that as of the patents' filing date (February 2, 1999), 21 U.S.C. §348(a) "*prohibited* using any sterilant (e.g., oxonia) in aseptic processing *unless* it was expressly allowed by the FDA for that purpose". Nestle's Surreply Markman Brief ([292] in 13-cv-892), p. 8 (emphasis in original). Steuben replies that "[f]ar from 'prohibiting' the use of oxonia, §348 actually provided a roadmap for how to go about obtaining 'approval' for oxonia's use as an aseptic packaging sterilant". Steuben's Response [476], p. 2.

Steuben suggests that "in order to gain acceptance of oxonia for use as an aseptic sterilant as described in Steuben's patents, a food additive petition could have been filed with the FDA - which would have resulted in the issuance of a regulation or food contact notification". Id., p. 5. "Under 21 U.S.C. §§ 348(a)(3)(A)-(B), a food additive is deemed to be safe for a particular use if there is a regulation or food contact notification in place prescribing the conditions under which that food additive may safely be used. Section 348(b)(1) provides that a petition can be submitted to the FDA to propose the issuance of a regulation prescribing the

[7] The only exception is the action against Jasper Products, LLC (13-cv-1118), which was commenced on November 14, 2013.

conditions for a specific use of a food additive. If the petition is granted, the FDA will promulgate a regulation. Similarly, §348(h)(1) provides that a manufacturer or supplier of a substance can obtain a food contact notification under §348 by identifying the substance and notifying the FDA that the substance is safe for a particular use. If the notice is not objected to within 120 days - the substance will be deemed safe as a food additive for the particular use identified." Id., p. 3.

Steuben overlooks several key and undisputed facts. In the first place, the "food contact notification" ("FCN") option was *not available* on February 2, 1999, when Taggart applied for the patents. "The FCN program began operating on October 22, 1999, with the signing of FDA's Fiscal Year 2000 budget. This budget met the requirements under section 409(h)(5) of the act [21 U.S.C. §348(h)(5)] for funding the FCN program. On October 25, 1999, FDA sent letters to trade associations and persons with pending submissions . . . . The letter stated that FDA expected to be ready to accept new FCNs on January 18, 2000." Food Additives: Food Contact Substance Notification System, 67 Fed. Reg. 35724-01.

Secondly, 21 U.S.C. §348(h)(1) mandated that the FCN "contain . . . all information required to be submitted by regulations promulgated by the Secretary", yet those regulations [21 C.F.R. Part 170.100-106] did not take effect until June 20, 2002. 67 Fed. Reg. 35724-01; *see also* "Regulatory Report: FDA's Food Contact Substance Notification Program" [453-5], CM/ECF p. 2 of 7.[8]

Finally, if Taggart had wished to petition for a new regulation (as opposed to a FCN) approving the use of oxonia as the sterilant, his petition would have had to include: "its chemical identity and composition . . . all directions, recommendations, and suggestions

[8] A FCN for the use of oxonia as a sterilant was not issued until September 24, 2006. [427-8], p. 81 of 139 (CM/ECF pagination).

proposed for the use of such additive . . . all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect . . . a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and . . . full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations." 21 U.S.C. §348(b)(2)(A)-(E).

Since Taggart admittedly knew nothing about "the effectiveness of peracetic acid and . . . hydrogen peroxide alone or together", nor "the amount of each component required to act as a sterilant" ([427-11], p. 232), had never tested oxonia for use as a sterilant in his invention (id., p. 167), and knew that "much more testing that would be required" (id., p. 198), there is simply no way that by February 2, 1999 he could have petitioned - much less *successfully* petitioned - for a new regulation allowing the use of oxonia as the sterilant.

B. Did Taggart Adequately Describe the Invention Defined in Claim 40 of the '188 Patent?

"[E]ach claim must be considered as defining a separate invention." Jones v. Hardy, 727 F.2d 1524, 1528 (Fed. Cir. 1984). Of the currently pending claims of the patents in suit, only claim 40 of the '188 patent expressly requires the use of oxonia as the sterilant for purposes of "aseptically disinfecting". *See* [426-3], CM/ECF pp. 27, 30 ("aseptically disinfecting the plurality of bottles . . . wherein the sterilant is peroxyacetic acid and hydrogen peroxide"). [9]

35 U.S.C. §112(a) requires the patent specification to "contain a written description of the invention". That requirement "plays a vital role in curtailing claims that . . .

[9] Although claim 12 of that patent also mentioned oxonia ([426-3], col. 16, l. 16-17), that claim was cancelled during reexamination. Id., p. 28, col. 2, l. 49.

have not been invented, and thus cannot be described". Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010). Therefore, determining compliance with the written description requirement necessarily entails "the fundamental issue [of] whether [the inventor] actually invented the subject matter it claimed". University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 930, n. 10 (Fed. Cir. 2004).

"Conception is the touchstone of invention." In re VerHoef, 888 F.3d 1362, 1366 (Fed. Cir. 2018). "Conception requires proof that the inventor formed in *his* mind a definite and permanent idea of the complete and operative invention . . . and that the idea be so clearly defined *in the inventor's mind* that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1365 (Fed. Cir. 2001) (emphasis added). Therefore, the court must "look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in *their* minds the required definite and permanent idea". Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F.3d 1223, 1232 (Fed. Cir. 1994) (emphasis added).

That "definite and permanent idea" must be fixed in the inventor's mind by the application filing date - in this case, February 2, 1999. *See* Ariad Pharmaceuticals, 598 F.3d at 1351 ("the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date"); TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111, 1118 (Fed. Cir. 2001) (inventor must be "in full possession of the claimed subject matter on the application filing date").

"Since possession is an element of conception, the inventor is therefore required to understand how to make and use the invention before a conception is said to occur." 2 Moy's

Walker on Patents §8:50 (4th ed.). "In other words, part of the conception inquiry asks whether the inventor possessed an operative method of making the invention." Dawson v. Dawson, 710 F.3d 1347, 1356 (Fed. Cir. 2013) (emphasis added).[10] The word "operative" means "producing an appropriate or designed effect", or "having the power of acting". Merriam-Webster Unabridged Online Dictionary (http://unabridged.merriam-webster.com).

Moreover, the inventor must have conceived "*every feature* of the subject matter sought to be patented". VerHoef, 888 F.3d at 1366 (emphasis in original). The use of oxonia as the sterilant is a limitation in claim 40, and "every limitation is material . . . to defining the scope of the patented invention". DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1016-17 (Fed. Cir. 2006). Therefore, the critical question is whether, as of February 2, 1999, Taggart had "formed in *his* mind a definite and permanent idea of the complete and operative"[11] use of oxonia as a sterilant which could receive FDA approval, and whether that idea was "so clearly defined in [his] mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation". Id.

Taggart has answered that question himself, and the answer is clearly no. He admitted he would have had to conduct "much more testing" to determine oxonia's suitability as a sterilant. [427-11], p. 198. As previously discussed (pp. 6-7, *supra*), FDA approval for the use of oxonia would have required a new FDA regulation - which, in turn, would have required a detailed petition containing detailed information as to "its chemical identity and composition", the "quantity of such additive required", and "full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used

[10] While the inventor "need not know that his invention will work for conception to be complete . . . there is a critical difference between conceiving a way to make an idea operative and knowing that a completed invention will work for its intended purpose". Id.

[11] Purdue Pharma, 237 F.3d at 1365.

in conducting such investigations". 21 U.S.C. §348(b)(2)(A)-(E). Since he had neither used nor tested oxonia as a sterilant, Taggart had none of this information. Therefore, at the time of filing he could not have obtained FDA approval for the use of oxonia as the sterilant. "[W]hen a claim requires a means for accomplishing an unattainable result . . . the claim must be held invalid." Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983).

At the Markman hearing, Steuben argued that "those skilled in the art in 1999 well knew that oxonia could be used as a sterilant, that it was coming . . . . [Taggart] knew it was coming, and he described it in his patent . . . . he recognized it was coming, he claimed it." [485], pp. 29, 34, 88. However, in determining inventorship, there is a critical difference between what "is coming" and what has arrived. *See* Medtronic Navigation, Inc. v. BrainLab Medizinische Computersysteme GmbH, 222 Fed. App'x 952 (Fed. Cir. 2007), involving the question of whether an inventor could claim to have invented an "optical tracking system" which he mentioned in his specification. In concluding he could not, the court reasoned:

> "[I]t is true that the minimal one sentence reference to an optical tracking system is a mention of an optical tracking system. However, the remainder of the specification describes acoustic systems . . . . [T]he inventor himself stated . . . that 'we weren't aware of any commercial optical tracking system that was available' and 'it seemed at the time that this would be an obvious development, that it would be coming in time. It was just that *at this time that we were writing this, that such a system wasn't available to us*' Thus, rather than being a disclosure of an optical system sufficient to support . . . a claim as including an optical system, it was merely an attempt to preempt the future before it has arrived." Id. at 956-57 (emphasis in original).

Like the inventor in Medtronic, Taggart's alleged belief that that FDA approval for oxonia "was coming" ([485], pp. 34, 88) was nothing more than "an attempt to preempt the future before it has arrived". Medtronic, 222 Fed. App'x. at 957; Ariad Pharmaceuticals, 598 F.3d at 1353.

I recognize that patent invalidity must "be proved by clear and convincing evidence". Microsoft Corp. v. i4i Limited Partnership, 564 U.S. 91, 95 (2011). However, while "[c]ompliance with the written description requirement [of 35 U.S.C. §112(a)] is a question of fact", it is "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party". Streck, Inc. v. Research & Diagnostic Systems, Inc., 665 F.3d 1269, 1285 (Fed. Cir. 2012).

This is such a case. For purposes of claim 40 of the '188 patent, Taggart's own testimony clearly and convincingly demonstrates that he did not invent the use of oxonia as a sterilant in a manner which could obtain FDA approval. Since "every limitation is material . . . to defining the scope of the patented invention" (DePuy Spine, 469 F.3d at 1016-17), if Taggart did not invent the oxonia limitation (and he did not), then he likewise did not invent claim 40. Since he did not invent that claim, then it is invalid under 35 U.S.C. §112(a), because "claims that have not been invented . . . cannot be described". Ariad Pharmaceuticals, 598 F.3d at 1353. For these reasons, I recommend that claim 40 of the '188 patent be declared invalid.

C. The Meaning of "Aseptically Disinfecting" in Claims That Do Not Mention Oxonia

35 U.S.C. §282(a) provides that "[e]ach claim of a patent . . . shall be presumed valid independently of the validity of other claims". Therefore, I must still consider whether my recommendation to invalidate claim 40 of the '188 patent also requires invalidation of the other "aseptically disinfecting" claims.

A claim term can have "different meanings in different claims based on those claims' different . . . contexts". Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 782 (Fed. Cir. 2010). Unlike claim 40 of the '188 patent, some "aseptically disinfecting" claims identify the sterilant as hydrogen peroxide - *e.g.*, '013 patent [1-1], claim 1 ("aseptically

disinfecting the bottles at a rate greater than 100 bottles per minute wherein the disinfecting is with hot atomized hydrogen peroxide"), and defendants "wholeheartedly agree that the claims that explicitly require hydrogen peroxide and, therefore, do not cover oxonia should survive this validity challenge." September 19, 2018 oral argument [532], p. 31. However, other "aseptically disinfecting" claims do not identify the sterilant - *e.g.*, '013 patent [1-1], claim 19 ("aseptically disinfecting the bottles at a rate greater than 100 bottles per minute"); *see also* the specification (id., col. 8, l. 17-18), referring to "hydrogen peroxide, oxonia, or any other suitable aseptic sterilant".

Steuben suggests that "if the Court does not find that Steuben has raised genuine issues of fact [as to the validity of claim 40 of the '188 patent], it would be appropriate to narrow the construction of 'aseptically disinfecting' to include only the use of hydrogen peroxide". Steuben's Memorandum in Opposition [521], p. 34. I agree, since "if possible . . . claims should be construed to sustain their validity". Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999). Therefore, those "aseptically disinfecting" claims which do not identify the sterilant should be construed to preserve their validity by limiting the sterilant to hydrogen peroxide, the only sterilant which *has* been properly described. *See* Medtronic 222 Fed. App'x at 956 ("[b]ecause this case is one in which ambiguity as to the scope of the claim language can be resolved in a manner that would preserve the patent's validity . . . that principle can properly be applied here").

CONCLUSION

For these reasons, I recommend that the defendants' motions for summary judgment be granted to the extent of invalidating claim 40 of the '188 patent and limiting the sterilant in the other "aseptically disinfecting" claims to hydrogen peroxide, but otherwise be

denied. Unless otherwise ordered by Judge Wolford, any objections to this Report and Recommendation must be filed with the clerk of this court by October 15, 2018 . Any requests for extension of this deadline must be made to Judge Wolford. A party who "fails to object timely . . . waives any right to further judicial review of [this] decision". Wesolek v. Canadair Ltd., 838 F. 2d 55, 58 (2d Cir. 1988); Thomas v. Arn, 474 U.S. 140, 155 (1985).

Moreover, the district judge will ordinarily refuse to consider *de novo* arguments, case law and/or evidentiary material which could have been, but were not, presented to the magistrate judge in the first instance. Patterson-Leitch Co. v. Massachusetts Municipal Wholesale Electric Co., 840 F. 2d 985, 990-91 (1st Cir. 1988).

The parties are reminded that, pursuant to Rule 72(b) and (c) of this Court's Local Rules of Civil Procedure, written objections shall "specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for each objection . . . supported by legal authority", and must include "a written statement either certifying that the objections do not raise new legal/factual arguments, or identifying the new arguments and explaining why they were not raised to the Magistrate Judge". Failure to comply with these provisions may result in the district judge's refusal to consider the objections.

Dated: October 1, 2018

/s/ Jeremiah J. McCarthy
JEREMIAH J. MCCARTHY
United States Magistrate Judge